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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Caplan <i>et al.</i>	Examiner:	Huynh
Serial No.:	10/728,051	Art Unit:	1644
Filing Date:	December 4, 2003	Conf. No.:	9832
Title:	MICROBIAL DELIVERY SYSTEM		

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF UNDER 37 C.F.R. § 41.41

Appellant submits the present Reply Brief in response to the Examiner's Answer mailed May 26, 2010, in the above-referenced case. The deadline for submitting the Reply Brief is July 26, 2010. Appellant, thus, submits that the Reply Brief is timely submitted on Monday, July 26, 2010.

Status of Claims (37 C.F.R. § 41.37(c)(1)(iii))

The present application is a divisional of U.S.S.N. 09/731,375, filed on December 6, 2000. The present application was filed on December 4, 2003, with claims 1-36.

Claims 1-33 were cancelled and new claims 34-42 were added by a Preliminary Amendment filed on December 4, 2003.

Claims 1-33 were the subject of a Restriction Requirement mailed March 11, 2005. The Restriction Requirement identified 22 Groups of claims. Appellant responded to the Restriction Requirement on March 24, 2005, noting that claims 1-33 had been canceled and new claims 34-42 had been added in the Preliminary Amendment filed on December 4, 2003. Appellant further noted that claims 34-42 appeared to fall within the subject matter of Group 12 of the Restriction Requirement, made an election of Group 12, and requested that claims 34-42 be examined in the present application.

Claims 34-42 were examined and rejected in an Office Action mailed May 4, 2005. A Response was filed on November 4, 2005, with claim amendments, including amendments adding new claims 43-45. Claims 34-45 were finally rejected in an Office Action mailed on July 18, 2006. A Response was filed on November 1, 2006, with claim amendments. Claims 34-45 were rejected in an Office Action mailed on January 31, 2007. A Notice of Appeal was filed on July 30, 2007. A Request for Continued Examination and Response to the January 31, 2007, Office Action was filed on February 29, 2008, with claim amendments. Claims 34-45 were rejected in an Office Action mailed on April 16, 2008. A Response was filed on October 26, 2008, with no claim amendments. Claims 34-45 were finally rejected in an Office Action mailed on January 26, 2009. A Notice of Appeal was filed on July 27, 2009. Thus, claims 34-45 are pending and stand rejected. The rejection of claims 34-45 was appealed, and an Appeal Brief was filed on March 1, 2010. The Examiner mailed an Examiner's Answer on May 26, 2010, in which all rejections were maintained. Appellant responds to the Examiner's Answer in this Reply Brief.

Grounds of Rejection To Be Reviewed upon Appeal (37 C.F.R. § 41.37(c)(1)(vi))

The grounds of rejection to be reviewed upon appeal are (referring to §§ 3-7 of the Office Action mailed on January 26, 2009):

(1) Are the pending claims obvious in light of the prior art (see §§ 3-5 of the Office Action mailed on January 26, 2009)? More specifically the Examiner raised the following sub-issues in the Office Action:

(a) Are claims 34-43 obvious in light of PCT Publication Number WO 99/38978 (“the ‘978 publication”) in view of Fenton *et al.* (1995, *J. Natl. Cancer Inst.*, 87:1853-61), Vrtala *et al.* (1995, *Int. Arch. Allergy Immunol.*, 107:290-94), U.S. Patent Number 5,888,799 (“the ‘799 patent”), U.S. Patent Number 3,097,141 (“the ‘141 patent”), and Leclerc *et al.* (1990, *J. Immunol.*, 144:3174-82) (see § 4)?

(b) Are claims 44-45 obvious in light of PCT Publication Number WO 99/38978 in view of Fenton *et al.* (1995, *J. Natl. Cancer Inst.*, 87:1853-61), Vrtala *et al.* (1995, *Int. Arch. Allergy Immunol.*, 107:290-94), U.S. Patent Number 5,888,799 (“the ‘799 patent”), U.S. Patent Number 3,097,141 (“the ‘141 patent”), and Leclerc *et al.* (1990, *J. Immunol.*, 144:3174-82), as applied to claims 34-43 (see § 4), and further in view of PCT Publication Number WO 92/14487 (“the ‘487 publication”) and U.S. Patent Number 6,270,723 (“the ‘723 patent”), Komanapalli *et al.* (1998, *Appl. Microbiol. Biotechnol.*, 49:766-69), and/or Ingram *et al.* (1980, *J. Bacteriol.*, 144:481-88) (see § 5)?

(2) Are pending claims 34-45 unpatentable over claims 34-36 and 38-49 of co-pending application U.S. Serial No. 10/728,323 under the judicially created doctrine of obviousness-type double patenting (see §§ 7-8)?

These grounds of rejection to be reviewed upon appeal were addressed in the Appeal Brief submitted on March 1, 2010. The Examiner’s Answer, mailed on May 26, 2010, indicated that all of these grounds of rejection are maintained.

Argument (37 C.F.R. § 41.37(c)(1)(vii))

The Examiner's Answer, mailed May 26, 2010, says that it "maintains" the levied rejections under 35 U.S.C. § 103. However, in fact, the Examiner has completely re-cast the rejections. As Appellant explained in the Appeal Brief, in the past, the Examiner has not *substantively responded* to Appellant's points and evidence, but rather has simply repeated prior conclusions and re-pasted prior text (even if no longer relevant). Happily, the Examiner's Answer takes a different approach, offering genuine responses to at least some of Appellant's points.

While Appellant appreciates the Examiner's effort and recognizes it as progress in the examination of this case, the current articulation of the rejections makes completely different points, and cites to completely different sections of the relevant art, so that, essentially, the Examiner has levied completely new rejections. Having not seen these points before, Appellant has not had an opportunity to address them on the record during regular prosecution. Appellant, therefore, respectfully submits that the Board would not have a proper record to consider, and would likely then need to remand the case back to the Examiner to allow prosecution to proceed. Appellant therefore is responding to the Examiner's new rejections by submitting a Continuation application. Preliminary Remarks will follow shortly, addressing the Examiner's new points.

Appellant further points out that the kind of substantive response provided in the Examiner's Answer is *precisely* the type of guidance that Appellant has repeatedly requested, and that the MPEP, statutes and regulations require. Unfortunately, the Examiner's long delay in providing such guidance has significantly harmed the Appellant by depriving them of the opportunity to progress prosecution. Appellant therefore respectfully submits that the Examiner's Answer should be considered to be the first substantive Action mailed by the United States Patent and Trademark Office since Appellant's first submitted Office Action Response addressing the rejection under 35 U.S.C. § 103 for purposes of calculating Patent Term Adjustment. under 35 U.S.C. § 154. Appellant, therefore, respectfully reserves the right to challenge any determination of patent term adjustment. Moreover, the present claims are directed to a product for which Food and Drug Administration has approved an Investigational New Drug Application and that is currently undergoing clinical trials. Appellant, therefore, respectfully notes that the delay caused by the Examiner's failure to provide proper examination is also costing Appellant Patent Term Extension under 35 U.S.C. § 156; Appellant reserves all

rights associated with any future attempts to recover Patent Term Adjustments and/or Patent Term Extension with respect to this case.

Respectfully submitted,

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